UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES M. MUSSER and VIVEK KAPUR

Appeal No. 2004-1662
Application No. 08/160,965

HEARD: November 16, 2004

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1, 4 through 35, 46, and 47, which are all of the claims remaining in the application.

Representative Claim

Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

1. An immunological composition comprising:

a physiologically acceptable non-toxic vehicle containing a purified non-proteolytic streptococcal pyrogenic exotoxin B (SPEB), which produces an immune response in a mammal against Group A streptococcal infection, wherein said SPEB comprises at least one amino acid substitution and said amino acid substitution occurs

at the amino acid position selected from the group consisting of Lysine145 (Lys145), Glutamine185 (Gln185), Cysteine192 (Cys192), Histidine340 (His340), Asparagine356 (Asn356) and Trytophan357 (Trp357).

The Issue

The issue presented for review is whether the examiner erred in rejecting claims 1, 4 through 35, 46, and 47 under 35 U.S.C. § 112, first paragraph, as based on a specification which does not provide adequate, written descriptive support for the invention now claimed.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) the amended Appeal Brief received December 16, 2003; (3) the Examiner's Answer mailed March 25, 2004; (4) the Reply Brief received May 24, 2004; (5) the Kapur et al. publication[1] cited and relied on by applicants in the amended Appeal Brief; and (6) the Tai et al. publication[2] cited in the specification, page 32, line 11; and discussed in the Examiner's Answer, paragraph bridging pages 4 and 5, and paragraph bridging pages 8 and 9.

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[1] Kapur et al. (Kapur), "A Conserved Streptococcus pyogenes Extracellular Cysteine Protease Cleaves Human Fibronectin and Degrades Vitronectin," Microbial Pathogenesis, Vol. 15, pp. 327-346 (1993)

[2] Tai et al. (Tai), "Primary Structure of Streptococcal Proteinase," The Journal of Biological Chemistry, Vol. 251, No. 7, pp. 1955-1959 (1976)

On consideration of the record, including the above-listed materials, we affirm the examiner's rejection under 35 U.S.C. § 112, first paragraph.

Procedure

Initially, we note applicants' Reply Brief including "the attached [amino acid] sequences that were obtained from GenBank" (Reply Brief, page 2, first paragraph). As stated in previous Rule 195 (37 CFR § 1.195), in effect when the Reply Brief was filed,

> **Affidavits or declarations after appeal.**
>
> Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

Here, we find no "showing of good and sufficient reasons" why the exhibits attached to applicants' Reply Brief were not earlier presented. Nor is there any indication that the examiner admitted those exhibits.[3]

In our judgment, the only plausible interpretation which these facts permit is that the exhibits, attached to applicants' Reply Brief, are not of record. Accordingly, we have considered the argument presented in the Reply Brief; but have not considered the exhibits (attachments) as evidence of record. See In re Scarbrough, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974) (Argument of counsel cannot take the place of evidence lacking in the record). Cf. In re Mehta, 347 F.2d 859, 866, 146 USPQ 284,

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[3] In an Office communication mailed June 16, 2004, the examiner states that "[t]he Reply Brief . . . has been entered and considered." However, the examiner does not indicate whether the exhibits have been entered.

289 (CCPA 1965) (Unsworn "Exhibit" can be taken merely as argument and not to establish facts).

Likewise, we note applicants' reference to the "accompanying amendment" in the Reply Brief, page 2, fifth line from the bottom. As stated in 37 CFR § 1.116(c):

> If amendments touching the merits of the application or patent under reexamination are presented after final rejection, or after appeal has been taken, or when such amendment might not otherwise be proper, they may be admitted upon a showing of good and sufficient reasons why they are necessary and were not earlier presented.

Again, we find no "showing of good and sufficient reasons why they [the proffered amendments] are necessary and were not earlier presented." Again, the record does not reflect that the examiner entered applicants' proffered amendment. Accordingly, in our deliberations, we have considered the claims and the record as they appeared at the time of the appeal.

The Merits

In considering the merits, we first note applicants' statement that "[t]he claims stand or fall together" (Amended Appellant Brief, page 2, last line; page 10, fifth line from the bottom). Accordingly, for the purposes of this appeal, we shall treat claims 4 through 35, 46, and 47 as standing or falling together with claim 1.

Oral Hearing

On November 16, 2004, Thomas D. Paul, Esq. presented oral argument on behalf of applicants. At the hearing, counsel acknowledged that claim 1 lacks written

descriptive support in the original specification (35 U.S.C. § 112, first paragraph), in view of the recitation "Glutamine185 (Gln185)."[4] For this reason alone, i.e., the inclusion of Glutamine185 (Gln185) in claim 1, we find that the examiner did not err in rejecting this claim under 35 U.S.C. § 112, first paragraph, as based on a specification which does not provide adequate, written descriptive support for the invention now claimed.

The Examiner's Principal Argument

We consider now the examiner's principal argument. According to the examiner, the immunological composition of claim 1 does not enjoy adequate, written descriptive support in the specification, as filed, because applicants do not describe the "reference sequence," i.e., the amino acid sequence of SPEB.

Applicants argue that the examiner has failed to consider the knowledge of persons skilled in the art at the time the invention was made. According to applicants, the complete amino acid sequence of SPEB - the "reference sequence" used to generate the invention of claim 1 - was in the public domain before the instant application was filed. Referring specifically to page 331, Figure 3 of Kapur et al., published in November 1993, applicants argue that they are not required to repeat the known "reference sequence" in their specification when that sequence was readily

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[4] Applicants proffered an amendment, concurrently with the filing of their Reply Brief, to delete Glutamine185 (Gln185) from the Markush group of enumerated amino acid positions in claim 1. However, as previously indicated, this record does not reflect that the examiner entered applicants' proffered amendment.

available to any person skilled in the art at the time the invention was made. See the Amended Appellant Brief received December 16, 2003, paragraph bridging pages 3 and 4; and page 4, first full paragraph. Applicants cite In re Chilowsky, 229 F.2d 457, 460, 108 USPQ 321, 324 (CCPA 1956) for the following proposition:

> It is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art. As was said in Webster Loom Co. v. Higgins, 105 U.S. 580, 586, 26 L.Ed. 1177, the applicant 'may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings.'

Id., page 4, last full paragraph.

According to the examiner, however, applicants are not in position to rely on "knowledge of persons skilled in the art at the time the invention was made;" or to argue that the complete amino acid sequence of SPEB (the "reference sequence") was in the public domain before the instant application was filed; or that the "reference sequence" was known and old at the time the invention was made. This follows, according to the examiner, because applicants expressly state that the published amino acid sequence for cysteine proteinase (SPEB) is incorrect (specification, page 20, lines 2 through 11; and page 24, lines 7 through 12). As stated by the examiner:

> The specification is quite clear in stating the instant ['reference'] sequence is unlike the sequences known in the prior art. However, the specification fails to disclose . . . the identity of the reference sequence from which the amino acids substitutions [sic] is based upon. [Examiner's Answer, page 4, last line, through page 5, line 3].

On this point, we agree with the finding that applicants' specification does not convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicants were in possession of the invention now recited in claim 1. Vas-Cath, Inc. v. Mahukar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Rather, in the judgment of this merits panel, the original specification is misdescriptive. Note particularly the passages appearing at page 20, lines 2 through 11; and page 24, lines 7 through 12. For example, at page 20, lines 2 and 3, applicants state that "[t]he published amino acid sequence for cysteine proteinase [SPEB] . . . is incorrect." Although not entirely clear, it may be that applicants intended to say that "the published amino acid sequence for cysteine proteinase [SPEB] was incorrect, until corrected by Kapur et al., Figure 3, before the effective filing date of the instant application;" and that the "correct" and complete amino acid sequence of SPEB was published in November 1993, by Kapur et al. If that were case, however, it is puzzling that applicants do not (1) cite Kapur et al. in their specification; or (2) rely on Figure 3 of Kapur et al. as support for their "reference sequence."

On these facts, we find that the examiner did not err in rejecting claim 1 under 35 U.S.C. § 112, first paragraph, as based on a specification which does not provide adequate, written descriptive support for the invention now claimed. We agree with the examiner's reasoning respecting the "reference" sequence, and we affirm the rejection of claim 1 essentially for those reasons set forth by the examiner. In so doing, we note the citation in the Examiner's Answer (page 5, lines 5 through 7) to the following passage in applicants' specification, page 32, lines 10 and 11:

> Targets for functional amino acid replacement are based on biochemical analysis of cysteine protease [SPEB] (Tai, et al., 1976).

However, as pointed out by the examiner (Examiner's Answer, page 5, lines 9 through 18):

> the sequence of Tai et al., fails to teach lysine at position 145 but rather an Arginine, a Glutamine at 185 but rather a Tyrosine, and a Cysteine at 192 but rather Valine. Furthermore the sequence of Tai et al., only shows an amino acid sequence through positions 252. And it is noted that this reference is not incorporated into the specification. Therefore, an analysis of [the Tai et al. publication] shows a completely different sequence making it doubtful that it contains the sequence from which the functional amino acid replacements are based upon. Without knowing the reference sequence, one cannot really know the significance of substituting amino acids at positions Lysine145, Glutamine185, Cysteine192, Histidine340, Asparagine356 and Trytophan357.

Additional Reasoning

> Claim 1 on appeal includes the following recitation:
>
> wherein said [non-proteolytic] SPEB comprises at least one amino acid substitution and said amino acid substitution occurs at the amino acid position selected from the group consisting of Lysine145 (Lys145), Glutamine185 (Gln185), Cysteine192 (cys192), Histidine340 (His340), Asparagine356 (Asn356) and Trytophan357 (Trp357).

Claim 1 calls for non-proteolytic SPEB comprising "at least one amino acid substitution" without specifying the nature of the amino acid substituent group. Claim 1 does, however, specify where amino acid substitution occurs, viz., "at the amino acid position selected from the group consisting of Lysine145 (Lys145), Glutamine185 (Gln185), Cysteine192 (Cys192), Histidine340 (His340), Asparagine356 (Asn356) and Trytophan357 (Trp357)." Applicants argue that support for the above-quoted recitation

may be found in the specification, as filed, page 32, line 13 through page 33, line 12. We disagree.

We have carefully reviewed page 32, line 13 through page 33, line 12 of the original specification. There, applicants describe a "targeted mutagenesis scheme" creating mutant forms of cysteine protease (SPEB). That passage in the specification, however, is more limiting than the amended language in claim 1 because the specification states that "[a]mino acids are changed to structurally neutral alanine" (original specification, page 32, line 18); and that "[s]ite-directed mutagenesis is used, by the charged-to-alanine-scanning method, to substitute positively and negatively charged amino acids . . . with alanine (id., page 33, lines 4 through 6). In addition, the specification states that "mutagenesis of Cys-192 may prevent autoproteolysis, as occurred for a Cys-⟩Ser mutant of papain, the prototype cysteine protease." Id., sentence bridging pages 32 and 33.

Applicants' position to the contrary, notwithstanding, we find that page 32, line 13 through page 33, line 12 of the specification, as filed, does not adequately support the broader language added by amendment to claim 1. Unlike the specification, the amended claim does not specify the nature of the amino acid substituent group but only specifies where amino acid substitution occurs.

In order to satisfy the written description requirement, the disclosure as originally filed must convey with reasonable clarity to persons skilled in the art that applicants were in possession of the invention now claimed. Vas-Cath, Inc. v. Mahukar, 935 F.2d at 1563-64, 19 USPQ2d at 1117 (Fed. Cir. 1991). Stated another way, any person

skilled in the art, reading the original disclosure, must "immediately discern the limitation at issue" in the claims. Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). On these facts, we disagree that the original disclosure, including page 32, line 13 through page 33, line 12, provides adequate, written descriptive support for the above-quoted recitation in claim 1. Any person skilled in the art, reading the original disclosure, would not "immediately discern the limitation at issue" in claim 1 which is broader than the descriptive passages in applicants' specification.

To the extent that applicants may argue the invention recited in claim 1 is not expressly disclosed, but would have been obvious over what is disclosed in the original specification, that is not the test. As stated in Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

> Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed.

Applicants must "describe" what is later set out in the claim, not merely subject matter that would be an "obvious variant" of what is later set out in the claim. Id., at 1572, 41 USPQ2d at 1966. "Possession" of the invention is shown by "describing the invention, with all its claimed limitations, not [by describing] that which makes it obvious." Id.

Conclusion

In conclusion, for the reasons set forth in the body of this opinion, we find that the examiner did not err in rejecting claim 1 under 35 U.S.C. § 112, first paragraph, as

based on a specification which does not provide adequate, written descriptive support for the invention now claimed. As previously indicated, claims 4 through 35, 46, and 47 fall together with claim 1.

The examiner's decision, rejecting claims 1, 4 through 35, 46, and 47, is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

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